

These instructions are recommended for the maintenance, disinfection, cleaning and sterilization of NICHROMINOX photo mirrors. This document has been created to assist healthcare personnel in the safe handling, maintenance and efficient reprocessing of NICHROMINOX photo mirrors to ensure the safety of the patient and the healthcare personnel.

1. DEVICE IDENTIFICATION

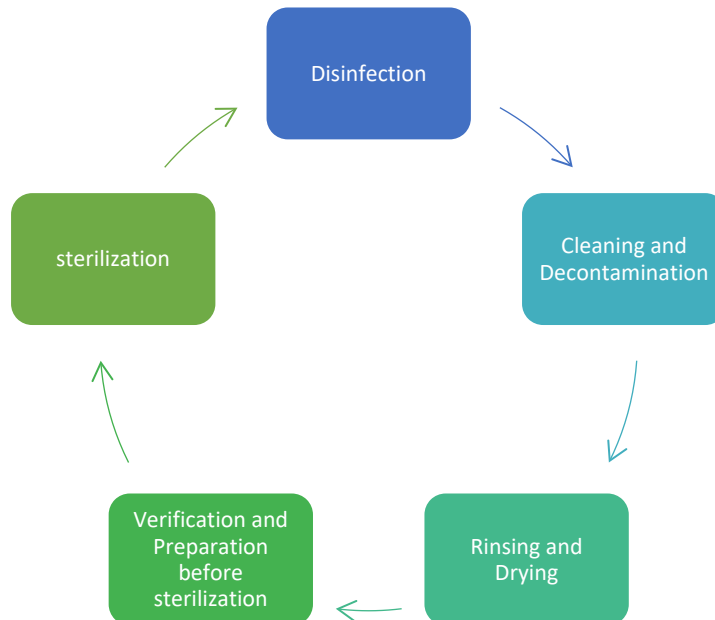
NICHROMINOX photo mirrors are intended for use by qualified dental professionals in a healthcare environment such as dental offices, hospitals, clinics and university laboratories.

These mirrors are made of vacuum metallized glass. They are intended for taking intraoral photos in indirect vision (References listed in the appendix).

The shape and size of the mirror used must correspond both to the area to be photographed as well as to the patient's morphology and behavior:

Type of mirrors	Big mouth	Small mouth	Zone		
			Palatine	Lateral	Lingual
Palatine - Ref. 190760 / Ref. 190792 / Ref. 190784	X		X		
Palatine narrow - Ref. 190761		X	X		
Lateral - Ref. 190762 / Ref. 190767 / Ref. 190791	X	X		X	
Lingual - Ref. 190764 / ref. 190765	X	X			X
Palatine XL - Ref. 190784	X		X		
Universal Large – Ref. 190785	X		X	X	X
Universal narrow – Ref. 190786		X	X	X	X
Universal XL – Ref. 190788	X	X	X	X	X

2. CLEANING AND STERILIZATION STEPS



Steps to follow:

Steps	Method	Precautions
Disinfection	Immerse in a bath of disinfection solution	Avoid putting them in a washing machine.
Cleaning and Decontamination	Ultrasonic bath →	The mirror should be placed in the bath in isolation to avoid scratches due to contact with other instruments.
	Thermo Washer →	It is recommended to place the mirrors on a suitable support for decontamination, in order to avoid possible damage due to the flow of products in the machine.
Rinsing and Drying	Rinse with distilled water, then dry. Use a drainage system.	Be sure to wipe it with a soft, lint-free cloth.
Verification and Preparation before sterilization	Check and remove excessively worn mirrors. Pack in a sachet or in a container suitable for sterilization.	Check the surface and edges as cracks may occur and cause breakage during use.
sterilization	The mirrors can be autoclaved: full cycle 134 ° C - 18 minutes + 20 minutes drying time.	Make sure they are completely dry when packing.

3. RESTRICTIONS

- **Warning:** for very toned patients, the mirrors may be subject to excessive mechanical stresses when the tongue is spreading, for example. It is preferable to use mirrors with metal handles or photo blades.
- **Never use** a mirror that is cracked or has significant scratches because the photograph will not be of good quality.
- **Never use** a mirror showing signs of shock or chipped because they could break in the mouth.
- **If stains are present**, only the NICHROMINOX Cleaning Kit (ref. 119960) will allow the traces to be easily removed.

To avoid fogging during use:

- Preheat the mirror (hot water, hair dryer)
- The saliva aspirator reduces humidity in the oral cavity
- The patient must breathe through the nose
- The patient can breathe in through the mouth
- Air spray can also remove fogging

4. PRECAUTIONS




These mirrors are used for their optical properties and like any such object, they should be handled with care to avoid scratches. Glass is sensitive to impact, especially at the edges. If a mirror has received an impact causing a shatter, it is a potential source of rupture, it should be scrapped immediately.




The same is true for a large scratch that you might feel when you brush your fingernail over the mirror.

An electrolysis phenomenon can occur in the event of immersion with other metals, which can go as far as the disappearance of the metallization.

5. SYMBOL AND LABELLING

LOT	Lot number
REF	Catalog number
MD	Medical Device

	Consult instruction for use
	Caution
	Complies with EU Regulation

	not been subjected to a sterilization process
	Manufacturing date
	Manufacturer

6. COMPLAINTS AND REQUESTS FOR INFORMATION

NICHROMINOX makes every effort to design and supply safe and high-performance devices, in accordance with its Quality policy. However, in the event of a serious incident occurring in connection with a NICHROMINOX device or in the event of a manufacturing defect, the healthcare professional (user, prescriber, etc.) or the patient must contact NICHROMINOX immediately.

Complaints or any other reason for dissatisfaction regarding NICHROMINOX devices must be indicated, specifying the reference, batch number and a full description of the incident.

For further information, please contact customer service directly via the contact details below:



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APPENDIX: References of Class I medical devices which must comply with this notice

Products concerned: Mirrors for intraoral photos

- Palatine Adult	Réf. 190760	- Palatine Adult	Réf. 190761	- Universal Large	Réf. 190785
- Palatine XL	Réf. 190784	- Lateral C	Réf. 190762	- Universal Etroit	Réf. 190786
- Lingual P	Réf. 190764	- Lateral S	Réf. 190763	- Universal XL	Ref. 190788
- Lingual G	Réf. 190765	- Lateral T1	Réf. 190767		
- Palatine AE + handle	Réf. 190792	- Lateral T1 + manche	Réf. 190791		